diameters and inner diameters and are axially aligned and adhered together in [the] an annular connection zone.

Sub B1 A2 cont.

11. (once amended) The implantable medical electrical lead of Claim [7]1, wherein the [ring-shaped electrode connector] coil electrode further comprises a ring-shaped member[is formed of a solid tube side wall with an opening through the side wall that the distal end of the lead conductor is extended into and attached to the side wall].

12. (once amended) The implantable medical electrical lead of Clam [7]1, wherein [the distal] a ring-shaped electrode is positioned distal from [to] the [wire] coil electrode.

13. (once amended) The implantable medical electrical lead of Clam [7]1, wherein [the distal] a ring-shaped electrode is positioned proximal from [to] the [wire] coil electrode.

II. Remarks

Support for the various amendments made to the claims herein may be found throughout the application as filed.

III. Rejections of Claims Made In the (First, Second) Office Action

In the communication from the Examiner mailed March 18, 2003, the Examiner rejected claims on the following bases:

(1) Claims 1-15 were rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

(2) Claims 1, 7 and 12-14 were rejected under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent No. 5,534,022 to Hoffman et al.; and

(3) Claims 1, 2, 4, 7, 8, 10 and 12 were rejected under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent No. 5,728,149 to Laske et al.; and

(4) Claims 2-4 and 8-10 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 5,534,022 to Hoffman et al.

(5) Claims 3, 9, 13 and 14 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 5,728,149 to Laske et al.

(6) Claims 5, 6, 11 and 15 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 5,534,022 to Hoffman et al. in view of U.S. Patent No. 5,728,149 to Laske et al.

Each of the foregoing rejections is responded to below, where each response references the number corresponding to each rejection set forth above.

IV. Responses to Rejections Made in the (First, Second) Office Action

(1) Claims 1-4 and 8-13 as amended herein overcome the rejections made under Section 112.

Claims 5-7, 14 and 15 are cancelled herein, rendering moot the rejections of those claims under Section 112.

As will be noted by reference to claims 1-4 and 8-13 as amended herein, such claims are amended herein to overcome the rejections made under the second paragraph of section 112.

(2) Claims 1-4 and 8-13 as amended herein are not anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,534,022 to Hoffman et al.

Claims 7 and 14 are cancelled herein, rendering moot the rejections of those claims under Section 102.

In rejecting claims 1, 7 and 12-14 the Examiner stated:

> Claims 1, 7 and 12-14 are rejected under . . . 102(b) as being anticipated by Hoffman et al . . . Due to the numerous 112 rejections, the examiner has interpreted the Hoffman reference as meeting the claimed limitations with reference to Figures 7 and 13. In addition, Hoffman is capable of meeting the functional use recitations presented in the claims.

Reference to claims 1-4 and 8-13 as amended herein will show that the invention now claimed contains limitations disclosed nowhere in the cited Hoffman reference. Amended claims 1-4 and 8-13 all include the limitations that the claimed device be directed to an implantable medical electrical lead for electrical stimulation of one or more sacral nerves of a human patient, where the lead comprises a coil electrode, the coil electrode being disposed at or near a distal portion of the lead and being electrically connected to a lead conductor, the coil electrode comprising an elongated flexible coiled wire extending between first and second coil ends, the distance between the first and second coil ends ranging between about 0.10 inches and about 1.50 inches, the coil electrode having an outer diameter not exceeding about 2.0 millimeters, wherein the coil electrode possesses sufficient mechanical flexibility and sufficiently small diameter to permit the distal portion of the lead to be inserted through a foramen of the patient's sacrum into a position near or in operative relation with at least one of the patient's sacral nerves without damaging or causing physical trauma to the at least one sacral nerve as the distal portion of the lead is being implanted by a physician in proximity thereto or after implantation of the lead has occurred, the coil electrode being configured to provide electrical stimulation to the at least one sacral nerve in an amount and manner sufficient to provide therapy for a pelvic floor disorder to the patient.

Nowhere does the cited Hoffman reference disclose such a sacral nerve stimulation lead. Indeed, review of the Hoffman reference shows that it is directed to an implantable cardiac defibrillation lead having a large electrode surface area that is specifically adapted to deliver the large amounts of energy required to defibrillate a

human heart (typically on the order of 10 to thirty joules), as well as for permitting low-impedance sensing of cardiac signals (see, for example, col. 3, lines 11-19, col. 4, lines 1-4, col. 4, lines 27-30 of the Hoffman reference).

Furthermore, the Hoffman reference teaches nothing concerning some of the problems solved by the present invention: Namely, providing a sacral stimulation lead and coil electrode possessing sufficient mechanical flexibility and sufficiently small diameter to permit the distal portion of a sacral stimulation lead to be inserted through a foramen of the patient's sacrum into a position near or in operative relation with at least one of the patient's sacral nerves without damaging or causing physical trauma to the at least one sacral nerve as the distal portion of the lead is being implanted by a physician in proximity thereto or after implantation of the lead has occurred, the coil electrode being configured to provide electrical stimulation to the at least one sacral nerve in an amount and manner sufficient to provide therapy for a pelvic floor disorder to the patient, even when the coil electrode has not been implanted at an "optimal" stimulation site in very close proximity to a sacral nerve.

Thus, it will now be seen that the Hoffman reference does not anticipate the invention recited in claims 1-4 and 8-13 because the basic requirement for anticipation is not met, namely, that all the elements recited in claims 1-4 and 8-13 be disclosed somewhere within the cited Hoffman reference. Thus, rejection of claims 1-4 and 8-13 as being anticipated by the Hoffman reference is overcome by the amendments made herein.

(3) Claims 1, 2, 4, 7, 8, 10 and 12 as amended herein are not anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,728,149 to Laske et al.

Claim 7 is cancelled herein, rendering moot the rejection of that claim under Section 102.

In rejecting claims 1, 2, 4, 7, 8, 10 and 12 the Examiner stated:

> Claims 1, 2, 4, 7, 8, 10 and 12 are rejected under . . . 102(b) as being anticipated by Laske et al.. . . Due to the numerous 112 rejections, the examiner has interpreted the Laske reference as meeting the claimed limitations with reference to Figures 7 and 13. In addition, Hoffman [Laske] is capable of meeting the functional use recitations presented in the claims.

Reference to claims 1, 2, 4, 7, 8, 10 and 12 as amended herein will show that the invention now claimed contains limitations disclosed nowhere in the cited Laske reference. Amended claims 1, 2, 4, 7, 8, 10 and 12 all include the limitations that the claimed device be directed to an implantable medical electrical lead for electrical stimulation of one or more sacral nerves of a human patient, where the lead comprises a coil electrode, the coil electrode being disposed at or near a distal portion of the lead and being electrically connected to a lead conductor, the coil electrode comprising an elongated flexible coiled wire extending between first and second coil ends, the distance between the first and second coil ends ranging between about 0.10 inches and about 1.50 inches, the coil electrode having an outer diameter not exceeding about 2.0 millimeters, wherein the coil electrode possesses sufficient mechanical flexibility and sufficiently small diameter to permit the distal portion of the lead to be inserted through a foramen of the patient's sacrum into a position near or in operative relation with at least one of the patient's sacral nerves without damaging or causing physical trauma to the at least one sacral nerve as the distal portion of the lead is being implanted by a physician in proximity thereto or after implantation of the lead has occurred, the coil electrode being configured to provide electrical stimulation to the at least one sacral nerve in an amount and manner sufficient to provide therapy for a pelvic floor disorder to the patient.

Nowhere does the cited Laske reference disclose such a sacral nerve stimulation lead. Indeed, review of the Laske reference shows that it, like the Hoffman reference, is directed to an implantable cardiac defibrillation lead having a coiled electrode specifically adapted to deliver the large amounts of energy required to defibrillate a human heart (typically on the order of 10 to thirty joules). See, for example, col. 3, lines 15-18, col. 4, lines 18-26, col. 7, lines 36-45, and col. 10, lines 13-18..

Furthermore, and like the Hoffman reference, the Laske reference teaches nothing concerning some of the problems solved by the present invention: Namely, providing a sacral stimulation lead and coil electrode possessing sufficient mechanical flexibility and sufficiently small diameter to permit the distal portion of a sacral stimulation lead to be inserted through a foramen of the patient's sacrum into a position near or in operative relation with at least one of the patient's sacral nerves without damaging or causing physical trauma to the at least one sacral nerve as the distal

portion of the lead is being implanted by a physician in proximity thereto or after implantation of the lead has occurred, the coil electrode being configured to provide electrical stimulation to the at least one sacral nerve in an amount and manner sufficient to provide therapy for a pelvic floor disorder to the patient, even when the coil electrode has not been implanted at an "optimal" stimulation in very close proximity to a sacral nerve.

Thus, it will now be seen that the Laske reference does not anticipate the invention recited in claims 1, 2, 4, 7, 8, 10 and 12 because the basic requirement for anticipation is not met, namely, that all the elements recited in claims 1, 2, 4, 7, 8, 10 and 12 be disclosed somewhere within the cited Laske reference. Thus, rejection of claims 1, 2, 4, 7, 8, 10 and 12 as being anticipated by the Laske reference is overcome by the amendments made herein.

(4) Claims 2-4 and 8-10 as amended herein are patentable under 35 U.S.C. Section 103(a) over U.S. Patent No. 5,534,022 to Hoffman et al.

Reference to claims 2-4 and 8-10 as amended herein will show that important new limitations have been introduced that are nowhere to be found in the cited Hoffman reference. More particularly, it will be noted that claims 2-4 and 8-10 as amended herein recite the following elements: (a) an implantable medical electrical lead for electrical stimulation of one or more sacral nerves of a human patient; (b) the lead comprising a an elongated flexible coiled wire electrode extending between first and second coil ends, the distance between the first and second coil ends ranging between about 0.10 inches and about 1.50 inches; (c) the coil electrode having an outer diameter not exceeding about 2.0 millimeters; (d) the coil electrode possessing sufficient mechanical flexibility and sufficiently small diameter to permit the distal portion of the lead to be inserted through a foramen of the patient's sacrum; (e) into a position near or in operative relation with at least one of the patient's sacral nerves; (f) without damaging or causing physical trauma to the at least one sacral nerve as the distal portion of the lead is being implanted by a physician in proximity thereto or after implantation of the lead has occurred; (g) the coil electrode further being configured to provide electrical stimulation to the at least one sacral nerve in an amount and manner sufficient to provide therapy for a pelvic floor disorder to the patient.

Comparison of the inventions recited in claims 2-4 and 8-10 as amended herein to the devices disclosed in the cited Hoffman reference will show that *none* of the elements recited above is disclosed therein. Instead, the Hoffman reference discloses a rather conventional cardiac defibrillation and sensing lead. Thus, significant modification of the devices disclosed in the cited Hoffman reference is required to arrive at the invention now recited in claims 2-4 and 8-10 as amended herein. In other words, the presently claimed invention cannot even be arrived at by combining the various elements disclosed in the Hoffman reference.

Limitations set forth in the present claims respecting the manner in which the present invention is adapted to stimulate one or more sacral nerves of a patient, even when the lead is not optimally implanted, and the manner in which its various mechanical and electrical components cooperate to provide therapy for pelvic floor disorders cannot properly be ignored by the Examiner. Those limitations, missing from the prior art, are part of the invention as a whole: they are not disclosed or suggested in the Hoffman reference, and provide important results and advantages not found in the prior art. Such limitations, therefore, cannot properly be ignored while other known features are focused on improperly with the benefit of hindsight for purposes of making an obviousness rejection.

The foregoing and other limitations are also important because the methods and materials disclosed in the cited Hoffman reference are totally unrelated to the problem solved by the present invention (namely, providing effective electrical stimulation therapy to a patient suffering from a pelvic floor disorder, even when the lead electrodes are not implanted in optimal stimulation sites).

The Applicants have discovered that a certain novel combination of mechanical and electrical elements, combined in a certain order and arranged in a certain manner, are required to produce the beneficial effects of the present invention. Those elements and arrangements are neither disclosed nor suggested anywhere in the cited Hoffman reference, and accordingly cannot be *prima facie* obvious.

(5) Claims 3, 9 and 13 as amended herein are patentable under 35 U.S.C. Section 103(a) over U.S. Patent No. 5,728,149 to Laske et al.

Claim 14 is cancelled herein, rendering moot the rejection of that claim under Section 103.

Reference to claims 3, 9 and 13 as amended herein will show that important new limitations have been introduced that are nowhere to be found in the cited Laske reference. More particularly, it will be noted that claims 3, 9 and 13 as amended herein recite the following elements: (a) an implantable medical electrical lead for electrical stimulation of one or more sacral nerves of a human patient; (b) the lead comprising a an elongated flexible coiled wire electrode extending between first and second coil ends, the distance between the first and second coil ends ranging between about 0.10 inches and about 1.50 inches; (c) the coil electrode having an outer diameter not exceeding about 2.0 millimeters; (d) the coil electrode possessing sufficient mechanical flexibility and sufficiently small diameter to permit the distal portion of the lead to be inserted through a foramen of the patient's sacrum; (e) into a position near or in operative relation with at least one of the patient's sacral nerves; (f) without damaging or causing physical trauma to the at least one sacral nerve as the distal portion of the lead is being implanted by a physician in proximity thereto or after implantation of the lead has occurred; (g) the coil electrode further being configured to provide electrical stimulation to the at least one sacral nerve in an amount and manner sufficient to provide therapy for a pelvic floor disorder to the patient.

Comparison of the inventions recited in claims 3, 9 and 13 as amended herein to the devices disclosed in the cited Laske reference will show that *none* of the elements recited above is disclosed therein. Instead, the Laske reference discloses a rather conventional cardiac defibrillation lead. Thus, significant modification of the devices disclosed in the cited Laske reference is required to arrive at the invention now recited in claims 3, 9 and 13 as amended herein. In other words, the presently claimed invention cannot even be arrived at by combining the various elements disclosed in the Laske reference.

Limitations set forth in the present claims respecting the manner in which the present invention is adapted to stimulate one or more sacral nerves of a patient, even

when the lead is not optimally implanted, and the manner in which its various mechanical and electrical components cooperate to provide therapy for pelvic floor disorders cannot properly be ignored by the Examiner. Those limitations, missing from the prior art, are part of the invention as a whole: they are not disclosed or suggested in the Laske reference, and provide important results and advantages not found in the prior art. Such limitations, therefore, cannot properly be ignored while other known features are focused on improperly with the benefit of hindsight for purposes of making an obviousness rejection.

The foregoing and other limitations are also important because the methods and materials disclosed in the cited Laske reference are totally unrelated to the problem solved by the present invention (namely, providing effective electrical stimulation therapy to a patient suffering from a pelvic floor disorder, even when the lead electrodes are not implanted in optimal stimulation sites).

The Applicants have discovered that a certain novel combination of mechanical and electrical elements, combined in a certain order and arranged in a certain manner, are required to produce the beneficial effects of the present invention. Those elements and arrangements are neither disclosed nor suggested anywhere in the cited Laske reference, and accordingly cannot be *prima facie* obvious.

(6) Claim 11 as amended herein is patentable under 35 U.S.C. Section 103(a) over U.S. Patent No. 5,534,022 to Hoffman et al. in view of U.S. Patent No. 5,728,149 to Laske et al.

Claims 5, 6 and 15 are cancelled herein, rendering moot the rejections of those claims under Section 103.

Reference to claim 11 as amended herein will show that important new limitations have been introduced that are nowhere to be found in the cited Hoffman and Laske references. More particularly, it will be noted that claim 11 as amended herein recites the following elements: (a) an implantable medical electrical lead for electrical stimulation of one or more sacral nerves of a human patient; (b) the lead comprising a an elongated flexible coiled wire electrode extending between first and second coil ends, the distance between the first and second coil ends ranging between about 0.10 inches and about 1.50 inches; (c) the coil electrode having an outer diameter not

exceeding about 2.0 millimeters; (d) the coil electrode possessing sufficient mechanical flexibility and sufficiently small diameter to permit the distal portion of the lead to be inserted through a foramen of the patient's sacrum; (e) into a position near or in operative relation with at least one of the patient's sacral nerves; (f) without damaging or causing physical trauma to the at least one sacral nerve as the distal portion of the lead is being implanted by a physician in proximity thereto or after implantation of the lead has occurred; (g) the coil electrode further being configured to provide electrical stimulation to the at least one sacral nerve in an amount and manner sufficient to provide therapy for a pelvic floor disorder to the patient.

Comparison of the invention recited in claim 11 as amended herein to the devices disclosed in the cited Hoffman and Laske references will show that *none* of the elements recited above is disclosed therein. Instead, the Hoffman and Laske references disclose rather conventional cardiac defibrillation leads. Thus, significant modification of the devices disclosed in the cited Hoffman and Laske references is required to arrive at the invention recited in claim 11 as amended herein. In other words, the presently claimed invention cannot even be arrived at by combining the various elements disclosed in the Hoffman and Laske references.

Limitations set forth in claim 11 respecting the manner in which the present invention is adapted to stimulate one or more sacral nerves of a patient, even when the lead is not optimally implanted, and the manner in which its various mechanical and electrical components cooperate to provide therapy for pelvic floor disorders cannot properly be ignored by the Examiner. Those limitations, missing from the prior art, are part of the invention as a whole: they are not disclosed or suggested in the Hoffman or Laske references, and provide important results and advantages not found in the prior art. Such limitations, therefore, cannot properly be ignored while other known features are focused on improperly with the benefit of hindsight for purposes of making an obviousness rejection.

The foregoing and other limitations are also important because the methods and materials disclosed in the cited Hoffman and Laske references are totally unrelated to the problem solved by the present invention (namely, providing effective electrical stimulation therapy to a patient suffering from a pelvic floor disorder, even when the lead electrodes are not implanted in optimal stimulation sites).

The Applicants have discovered that a certain novel combination of mechanical and electrical elements, combined in a certain order and arranged in a certain manner, are required to produce the beneficial effects of the present invention. Those elements and arrangements are neither disclosed nor suggested anywhere in the cited Hoffman and Laske references, alone or in combination, and accordingly cannot be *prima facie* obvious.

V. Summary

Claims 1-4 and 8-13 remain pending in the application, and are believed to be in condition for allowance. Examination of the application as amended is requested.

The Examiner is respectfully requested to contact the undersigned by E-mail at thomas.woods@medtronic.com with any questions or comments he may have. Applicant's attorney will promptly follow up the receipt of an E-mail from the Examiner with a phone call.

Respectfully submitted,

Date: June 26, 2003

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EXHIBIT A: CLEAN REPLACEMENT PORTIONS OF THE APPLICATION AS AMENDED HEREIN

1. An implantable medical electrical lead for electrical stimulation of one or more sacral nerves of a human patient, comprising:

a lead body extending between proximal and distal lead ends;

a proximal connector disposed at or near the proximal end of the lead body;

at least one lead conductor extending between the connector and a coil electrode, the coil electrode being disposed at or near a distal portion of the lead and being electrically connected to the lead conductor, the coil electrode comprising an elongated flexible coiled wire extending between first and second coil ends, the distance between the first and second coil ends ranging between about 0.10 inches and about 1.50 inches, the coil electrode having an outer diameter not exceeding about 2.0 millimeters;

wherein the coil electrode possesses sufficient mechanical flexibility and sufficiently small diameter to permit the distal portion of the lead to be inserted through a foramen of the patient's sacrum into a position near or in operative relation with at least one of the patient's sacral nerves without damaging or causing physical trauma to the at least one sacral nerve as the distal portion of the lead is being implanted by a physician in proximity thereto or after implantation of the lead has occurred, the coil electrode being configured to provide electrical stimulation to the at least one sacral nerve in an amount and manner sufficient to provide therapy for a pelvic floor disorder to the patient.

2. The implantable medical electrical lead of Claim 1, wherein the coil electrode and connector are operatively connected to one another in an annular connection zone.

3. The implantable medical electrical lead of Claim 1, wherein the coil electrode and connector are butt-welded together.

4. The implantable medical electrical lead of Claim 1, wherein the coil electrode and connector are adhered together.

8. The implantable electrical medical lead of Claim 1, wherein the coil electrode and connector have substantially common outer diameters and inner diameters and are axially aligned and coupled together in an annular connection zone.

9. The implantable medical electrical lead of Claim 1, wherein the coil electrode and connector have substantially common outer diameters and inner diameters and are axially aligned and butt-welded together in an annular connection zone.

10. The implantable medical electrical lead of Claim 1, wherein the coil electrode and connector have substantially common outer diameters and inner diameters and are axially aligned and adhered together in an annular connection zone.

11. The implantable medical electrical lead of Claim 1, wherein the coil electrode further comprises a ring-shaped member.

12. The implantable medical electrical lead of Clam 1, wherein a ring-shaped electrode is positioned distal from the coil electrode.

13. The implantable medical electrical lead of Clam 1, wherein a ring-shaped electrode is positioned proximal from the coil electrode.